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# INNOVATION, ACCESS AND THE PUBLIC'S HEALTH: INTELLECTUAL PROPERTY RIGHTS IN MEXICO AND THE TB EPIDEMIC

Pamela Das\*

PATENT laws have stirred a substantial amount of controversy on the international scene. The pharmaceutical industry views patent law as a necessary tool to encourage innovation and the development of new drugs, because profit incentives provide the pharmaceutical companies with a basis for investing in costly development processes.<sup>1</sup> On the other hand, many developing countries argue that implementing patent laws for pharmaceutical products should be prohibited because "access to pharmaceutical products is so important that the products themselves should not be patented."<sup>2</sup> Furthermore, the World Health Organization (WHO) notes that even with patent laws, a significant proportion of the world's population has yet to derive benefit from pharmaceutical innovation because of weak supply and price barriers.<sup>3</sup> From 1975 to 1999, drugs for diseases such as tuberculosis (TB) and malaria represented only sixteen of the 1393 drugs marketed.<sup>4</sup> Currently, 90 percent of pharmaceutical research and development (R&D) goes towards the health problems of 10 percent of the global population.<sup>5</sup> Much of the drug development goes toward lifestyle drugs, such as Rogaine, Viagra, and diet pills.<sup>6</sup> Much of the emphasis placed on lifestyle drugs is because of the narrow perspective of pharmaceutical companies. As a former Merck CEO put it, "there are more well people than sick people. We should make products for people who are well."<sup>7</sup> In addition to lifestyle

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1. John H. Barton, *TRIPS and the Global Pharmaceutical Market*, HEALTH AFFAIRS, May-June 2004, at 146.

2. *Id.* at 147.

3. 56TH WORLD HEALTH ASSEMBLY, *WHO Intellectual Property Rights, Innovation and Public Health*, Agenda Item 14.9, May 28 2003, <http://www.who.int/phi/A5617.pdf>.

4. Chenxi Jiao, *The Negative Effect of Pharmaceutical Patents on South African Industry*, 5 CARDOZO PUB. L. POL'Y & ETHICS J. 665, 665 (2007).

5. Peter Yu, *The International Enclosure Movement*, 82 IND. L.J. 827, 842 (2007).

6. *Id.*

7. *Id.*

drugs, there has also been significant investment in developing and refining drugs that address diseases prevalent in the developed world, such as cancer, diabetes, and heart disease.<sup>8</sup> While there has been some research into tropical diseases, much of the treatment has focused on prophylactic vaccines for people of the developed world who travel into foreign countries, instead of developing drugs for people in the developing world who actually suffer from the diseases.<sup>9</sup>

This Note focuses on the Mexican pharmaceutical industry because a strong relationship exists between the health of Mexico and the health of United States because of immigration. Furthermore, the North American Free Trade Agreement (NAFTA), which governs trade between Mexico and the United States, offers a unique perspective of how free trade agreements can shape international pharmaceutical policy. This Note looks specifically at the effects of pharmaceutical patents on anti-tuberculosis drugs, as this area is still unexplored. Part I of this Note gives an overview of tuberculosis at a global level, while Part II addresses the specific problem of TB in Mexico. Part III describes the current perspectives of how pharmaceutical patents affect access to medicine. Part IV recounts the historical rise of patents, and the subsequent pressure put on the international community to harmonize. Parts V, VI, and VII detail more specifically the implementation of global patent laws through NAFTA, TRIPS, and DOHA, respectively. This is followed by Part VIII, which describes the Mexican pharmaceutical market and its transformation after international patent laws were implemented. In the last major section, the Note attempts to hypothesize how international patent laws will affect the Mexican pharmaceutical industry and the Mexican population's access to TB drugs.

## I. THE GLOBAL CONTEXT OF TB

Tuberculosis continues to be a great public health problem to this day, and it kills "young and middle-aged adults faster than any other disease apart from [AIDS]."<sup>10</sup> "The World Health Organization estimates that one third of the world's population is infected with . . . tuberculosis."<sup>11</sup> In 2005, there were approximately 8.8 million new cases of tuberculosis and greater than 1.5 million deaths due to the disease.<sup>12</sup>

The pressing public health problem of tuberculosis demands the creation of new drugs and greater access to tuberculosis medications. When effective drugs are available, tuberculosis cure rates exceed 90 percent; however, in the absence of effective drugs or inadequate compliance with

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8. *Id.*

9. *Id.*

10. Richard J. O'Brien & Paul P. Nunn, *The Need for New Drugs Against Tuberculosis*, 167 AM. J. RESPIR'Y & CRIT. CARE MED. 1055, 1055 (2001).

11. Elizabeth A Talbot et al., *Tuberculosis Among Foreign-Born Persons in the United States, 1993-1998*, 284 J. AM. MED. ASS'N, 2894, 2894 (2000).

12. WHO Global Fact Sheet, <http://www.who.int/mediacentre/factsheets/fs104/en/>.

a TB drug regime, cure rates drop dramatically.<sup>13</sup> The fact that mortality rates from tuberculosis hover close to two million indicates that many people across the world “do not have access to or do not take effective treatment for this widespread disease.”<sup>14</sup>

The inability or reluctance of people to comply with a TB drug regime is creating a greater public health challenge of multidrug-resistant tuberculosis (MDRTB).<sup>15</sup> MDRTB is tuberculosis resulting from bacteria that are “resistant to at least isoniazid and rifampicin,”<sup>16</sup> two drugs that are considered essential medicines by the WHO.<sup>17</sup> Tuberculosis drug resistance can be broken down into two different types: primary resistance and acquired resistance.<sup>18</sup> Primary resistance occurs when an individual is infected with a drug resistant TB strain for the first time, while acquired resistance occurs when an individual shows resistance after a prior treatment.<sup>19</sup> The existence of primary resistance reveals a greater problem of “past programmatic frailties.”<sup>20</sup>

Global epidemiological evidence about MDRTB is sparse and under-researched.<sup>21</sup> With the current evidence based on data from sixty-four countries, however, the annual incidence of MDRTB was estimated to be 273,000 cases.<sup>22</sup> Future projections estimate that the annual incidence rate of drug resistant TB “may climb and that concerted efforts to control MDRTB will be required and make [sic] take years[,] if not decades[,] if rates are to decline.”<sup>23</sup>

## II. TUBERCULOSIS IN MEXICO AND THE U.S. PROBLEM

The epidemiology of tuberculosis in Mexico is of great concern to the United States, as the proportion of TB cases in its foreign-born population has increased from 21.6 percent to 61 percent between 1986 and 1992.<sup>24</sup> According to another study, from 1993 to 1998, 64 percent of new TB cases occurred among people born in the United States and 35.1 percent occurred in foreign-born individuals.<sup>25</sup> Approximately two-thirds of the foreign-born individuals having TB came from one of seven countries:

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13. Richard Laing & K.M. McGoldrick, *Tuberculosis Drug Issues, Prices, Fixed-Dose Combination Products and Second Line Drugs*, 4 INT'L J. TUBERCULOSIS & LUNG DISEASE 194, 102 (2000).
  14. *Id.*
  15. Richard Coker, *Review: Multidrug-Resistant Tuberculosis: Public Health Challenges*, 9 TROPICAL MED. & INT'L HEALTH 25, 25 (2004).
  16. *Id.*
  17. WHO Essential Medicine List, *supra* note 12.
  18. Coker, *supra* note 15, at 25.
  19. *Id.*
  20. *Id.*
  21. *Id.* at 26.
  22. *Id.*
  23. *Id.*
  24. Teresa N. Quitugua et al., *Transmission of Drug-Resistant Tuberculosis in Texas and Mexico*, 40 J. CLINICAL MICROBIOLOGY 2716, 2716 (2002).
  25. Talbot, *supra* note 11, at 2895.

Mexico, the Philippines, Vietnam, China, India, Haiti, and South Korea.<sup>26</sup> In Texas, California, and Illinois, Mexico was listed as the “most commonly reported birth country for foreign-born person with TB.”<sup>27</sup>

The Center for Disease Control and Prevention (CDC) estimates the incidence rate of tuberculosis in the United States in 2006 to be 5 cases per 100,000 people.<sup>28</sup> It further estimates that 124 cases of multidrug resistant cases of tuberculosis were reported in 2005.<sup>29</sup> By contrast, in Mexico the estimated TB incidence was 32 cases per 100,000 people, totaling 33,529 new cases of tuberculosis.<sup>30</sup> It is estimated that 2.4 percent of these cases are new multidrug-resistant TB cases.<sup>31</sup> Similar to the demographics of TB in other parts of the world, in certain parts of Mexico TB appears to disproportionately affect “the poor, illiterate, rural, and indigent populations.”<sup>32</sup>

Although the Direct Observation Treatment Short Course (DOTS) strategy implemented by the WHO has been essential in tackling TB on a global scale, in areas that are already plagued with a high prevalence of MDRTB, the success of DOTS seems more uncertain.<sup>33</sup> For example, in Southern Mexico studies indicate that one in three patients harbor resistant strains to at least one of the TB drugs, despite the relatively good TB control programs.<sup>34</sup> The major risk factors for the emergence of MDRTB in Mexico are inappropriate drug regimens that contain too few drugs and non-adherence to drug programs.<sup>35</sup> Other risk factors include “erratic drug supplies, substandard drug quality, and unrestricted access to anti-TB drugs through over-the-counter sales.”<sup>36</sup>

In Mexico, when a patient is diagnosed with TB a two-drug treatment regimen is initiated.<sup>37</sup> Although “the [Center for Disease Control] (CDC) and the American Thoracic Society recommend beginning . . . treatment with a four-drug regimen” to prevent MDRTB, cost plays a major role in limiting the regimen to less than four drugs.<sup>38</sup> “The current 3-drug regimen costs approximately \$120 per complete treatment” and

26. *Id.*

27. *Id.*

28. Center for Disease Control and Prevention, Trends in Tuberculosis Incidence—United States 2006 (March 23, 2007), available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5611a2.htm>.

29. *Id.*

30. USAID, *Tuberculosis Profile*, Mexico, [http://www.usaid.gov/our\\_work/global\\_health/id/tuberculosis/countries/lac/mexico.pdf](http://www.usaid.gov/our_work/global_health/id/tuberculosis/countries/lac/mexico.pdf).

31. *Id.*

32. Maria de Lourdes Garcia-Garcia et al., *Tuberculosis Epidemiology and Control in Veracruz, Mexico*, 28 INT’L J. OF EPIDEMIOLOGY 135, 139 (1999).

33. Maria de Lourdes Garcia-Garcia et al., *Clinical Consequences and Transmissibility of Drug-Resistant Tuberculosis in Southern Mexico*, 160 ARCHIVES INTERN. MED. 633, 633 (2000).

34. *Id.* at 633-34.

35. Rueben M. Granich et al., *Survey of Drug Resistance of Mycobacterium Tuberculosis in 3 Mexican States, 1997*, 160 ARCHIVES INTERN. MED. 639, 640 (2000).

36. *Id.*

37. *Id.* at 643.

38. *Id.*

adding the fourth drug "would increase this cost by approximately 30 [percent] per patient."<sup>39</sup>

TB drug development is not only necessary to reduce morbidity and mortality from MDRTB, but also to find a more effective first line treatment that will shorten the duration of total treatment and/or allow for "more widely spaced intermittent treatment," which would consequently increase compliance.<sup>40</sup> "The current tuberculosis treatments regimens, although highly effective, are far from ideal."<sup>41</sup> Even with the most "optimal combination of available drugs, the duration of treatment cannot. . .[go] below six months."<sup>42</sup> Furthermore, a patient on a TB regimen must take four medications together for at least the first two months and may consume more than ten tablets at one time.<sup>43</sup> Therefore, a drug compound that decreases duration and the frequency of drug administration is invaluable.<sup>44</sup>

In addition to the need for innovation of TB drugs, greater overall access to TB drugs is needed to combat the TB pandemic.<sup>45</sup> A major contributor to the lack of access is the price of drugs, which is influenced by a variety of factors, such as prices set by the manufacturer, custom duties, registration fees, taxes, and mark up values.<sup>46</sup> In the United States, over the past twenty years U.S. private market "prices for first-line drugs increased. . .[at] an average [rate] of 10.66 percent per year."<sup>47</sup>

### III. VIEWS ABOUT PATENTS AND ACCESS TO DRUGS

Many public health activists believe that implementing global patents for pharmaceuticals will greatly curtail access to essential medicines because it will drastically increase prices by creating a monopoly on drugs. Before discussing the implications of pharmaceutical patents on access to medicine, a working knowledge of essential medicines is necessary.<sup>48</sup> According to the World Health Organization, "[e]ssential medicines are those that satisfy the priority health care needs of the population[:]; [t]hey are selected with due regard to public health relevance, evidence of efficacy and safety, and comparative cost-effectiveness."<sup>49</sup> The WHO creates and updates the list of essential medications with the hopes that countries will implement their own national drug policies to make sure that these medications are available for their population at affordable

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39. *Id.*

40. O'Brien & Nunn, *supra* note 10, at 1056.

41. *Id.*

42. *Id.*

43. *Id.*

44. *Id.*

45. Laing, *supra* note 13, at 198.

46. *Id.* at 199.

47. *Id.* at 200.

48. Richard Laing et al., *Twenty Five Years of the WHO Essential Medicines List: Progress and Challenges*, 361 LANCET 1723, 1723 (2003).

49. *Id.*

prices.<sup>50</sup> Even with the existence of this list, however, nearly one-third of the world's population lacks access to these essential medicines.<sup>51</sup>

Many scholars argue that the patents are not responsible for the lack of access because 95 percent of the drugs listed on the essential medicines list are off-patent.<sup>52</sup> However, as Medecins Sans Frontieres (MSF), more commonly known as Doctors Without Borders, notes, many medicines that are life saving and essential are not on the essential medicine list because they are too expensive. Furthermore, the reason that many of these drugs are off-patent is because the patents have expired. If new drugs are developed they will be subject to patent protection and subsequently higher cost. In addition, even with off-patent TB drugs, the purchase price of these drugs can be feasibly dropped by 95 percent.<sup>53</sup>

Many claim that poverty, not patents, is the main contributor to lack of access.<sup>54</sup> Because developing countries contribute such little revenue to pharmaceutical companies, on many occasions pharmaceutical companies forgo patent protection.<sup>55</sup> Much of this analysis, however, focuses on the poorest African nations.<sup>56</sup> Middle income countries such as China, India, Mexico, and South Africa, are target economies for pharmaceutical companies; therefore, companies are less inclined to forgo patent protection within these countries, which consequently results in higher prices.<sup>57</sup> Overall, "[i]n Latin America the cost of medicines has increased at a rate faster than inflation."<sup>58</sup> In fact, despite a low per capita income, both Mexico and Chile had prices comparable to that of the United Kingdom.<sup>59</sup> The number of pharmaceuticals sold in many Latin American countries has decreased even though drug expenditures increased.<sup>60</sup> This discrepancy demonstrates that access to medicine is becoming more difficult.<sup>61</sup> Therefore, while poverty and lack of health care infrastructure greatly contribute to the lack of access, the effect of patents on drug prices is also a major consideration.

50. *Id.*

51. MSF Access Website, <http://www.accessmed-msf.org>.

52. Amir Attaran, *How Do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries?*, *HEALTH AFFAIRS* 155, 157 (2004).

53. Interview by Barbara Bogaev with Dr. Paul Farmer, Medical Anthropologist, Fresh Air from WHYY, NPR (Sept. 25, 2003), <http://www.npr.org/templates/story/story.php?storyId=1446061> (at timestamp 13:32).

54. Attaran, *supra* note 52, at 159.

55. *Id.*

56. *Id.*

57. *Id.*

58. Nuria Homedes & Antonio Ugalde, *Multisource Drug Policies in Latin America: Survey of Ten Countries*, 83 *BULL. WORLD HEALTH ORG.* 64, 64 (2005).

59. Patricia M. Danzon & Michael F. Furukawa, *Prices and Availability of Pharmaceuticals: Evidence from Nine Countries*, *HEALTH AFFAIRS* Web Exclusive, at 527-28 (2003), <http://content.healthaffairs.org/cgi/reprint/hlthaff.w3.521v1.pdf>.

60. Homedes & Ugalde, *supra* note 58, at 64.

61. *Id.*

#### IV. THE RISE OF PATENTS AND THE GROWING PRESSURE ON THE INTERNATIONAL COMMUNITY TO HARMONIZE

In the United States, patents have been the cornerstone of the protection of property rights and have served as a "tool to provide an incentive to technical progress."<sup>62</sup> Between 1981 and 2001 the number of patents in the United States increased from 71,000 to 184,000, which amounts to a 159 percent increase.<sup>63</sup> Although innovation has been a common justification for patenting, much of this increase is attributable to the intensification of patenting rather than the creation of new inventions.<sup>64</sup> In the 1990s, U.S. R&D increased by 41 percent, while the number of patents granted increased by over 72 percent.<sup>65</sup> For many, the intensification of patenting portrays a social good because it "stimulate[s] a flow of inventions. . .[and] promote[s] . . .commercialisation to the wider economic benefit of society."<sup>66</sup> But to others the proliferation of patents creates a cause for alarm because patents can possibly restrict access through higher prices and they can distort research priorities.<sup>67</sup>

Because the high prices of drugs can be attributed to patents, once a drug goes off-patent generic competition can decrease the price of the drug dramatically. In response to this potential competition, pharmaceutical companies have pursued expensive litigation "to delay or prevent generic entry and to protect or extend a monopoly on a bestselling drug."<sup>68</sup> Furthermore, the United States, under the strong pressure from pharmaceutical companies, has conveyed a growing of fear of generic producers internationally exporting drugs that pharmaceutical companies have spent millions of dollars to develop.<sup>69</sup> The United States also expressed the concern of drug smuggling across borders, since many drugs are not patented internationally and may be available for cheaper prices.<sup>70</sup> Therefore, the United States put pressure on the international community to harmonize patent laws and set minimum standards for patent protections that countries should respect.<sup>71</sup>

#### V. BEFORE TRIPS, CAME NAFTA: AN OVERVIEW OF NAFTA

One of the attempts to harmonize patent laws internationally occurred in 1994 with the implementation of the North American Free Trade

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62. COMMISSION ON INTELLECTUAL PROPERTY RIGHTS (U.K.), WIPO WTO TRIPS: INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY 112 (2002).

63. *Id.*

64. *Id.*

65. *Id.*

66. *Id.* at 113.

67. *Id.*

68. *Id.* at 36

69. Kristine Novak, *The WTO's Balancing Act*, 112 J. OF CLINICAL INVESTIG. 1269, 1269 (2003).

70. *Id.*

71. *Id.*



Agreement (NAFTA).<sup>72</sup> The provision most relevant to pharmaceutical drugs is Article 1709.<sup>73</sup> Article 1709 mandated the recognition of previously unrecognized patents for pharmaceutical products and processes. Article 1709(1) of NAFTA demands that signatory countries must patent "any invention whether products or processes in all fields of technology, provided that such inventions are new, result from an inventive step[,] and are capable of industrial application."<sup>74</sup> There are exceptions to patent rules, as seen in Article 1709 (3), which provides that a party can deny protection for certain "diagnostic, therapeutic[,] and surgical methods for the treatment of humans. . . [,] plants[,] and animals other than microorganisms."<sup>75</sup> Exceptions, such as Article 1709(3), were troubling to the United States because it feared that devices patentable in the United States would not be given the same patent protection in the member states.<sup>76</sup> But Article 1709(5) gives the patent holder the power to "prevent unauthorized parties from making, using[,] or selling subject matter of a product patent and [can] prevent unauthorized parties from using the process in selling, using[,] or importing products derived from [the] patent[ ] process."<sup>77</sup> This power is not unlimited, as Article 1709(6) permits signatory states to "provide limited exceptions to the exclusive rights conferred by a patent."<sup>78</sup> The exceptions, however, cannot be "unreasonably [in] conflict with normal exploitation of a patent" and must "not unreasonably prejudice legitimate interests of the patent owner, taking into account the legitimate interests of the other persons."<sup>79</sup>

Another relevant change that NAFTA made regarding pharmaceutical patents is the restriction on compulsory licensing.<sup>80</sup> Prior to NAFTA, Mexico would commonly use compulsory licensing as a way to make cheap generics.<sup>81</sup> But under Article 1709(7), signatory nations are restricted from free access to compulsory licensing.<sup>82</sup> Article 1709(10) modifies 1709(7) and grants compulsory licenses under limited circumstances.<sup>83</sup> For example, for a compulsory license to be granted the applicant "must have previously made an effort. . .to obtain authorization from the patent holder and must have their case considered individually before they would be allowed a compulsory license."<sup>84</sup> Under the current

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72. Gerardo Vazquez Gomez, *The Liberalisation of Financial Services in Mexico and its Relation with NAFTA, MEFTA and GATS*, 11 L. & BUS. REV. AM. 49, 51 (2005)

73. Arlene Noral Farolan, *Harmonization of Patent Systems of NAFTA Nations*, 10 CURRENTS: INT'L TRADE L.J. 54, 59 (2001).

74. *Id.* at 59.

75. *Id.* at 60.

76. *Id.*

77. *Id.*

78. *Id.*

79. *Id.*

80. *Id.*

81. *Id.*

82. *Id.*

83. *Id.*

84. *Id.*

Mexican pharmaceutical policy, compulsory licenses can be used only under limited circumstances.<sup>85</sup>

## VI. THE TRIPS AGREEMENT AND THE CREATION OF GLOBALIZED DRUG MARKET

In January 1995, through the initiative of the United States and other developed countries, the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement went into force in an attempt to change the international pharmaceutical landscape and achieve greater patent protection on a global scale.<sup>86</sup> The proponents of TRIPS were responding to pressure by pharmaceutical companies who "viewed themselves as victims of 'piracy' in many markets throughout the world and wanted to gain increased protection for their products."<sup>87</sup> The TRIPS agreement sets minimal guidelines for the protection of intellectual property rights that each member government must accord fellow World Trade Organization (WTO) members.<sup>88</sup>

One of the most pertinent provisions of TRIPS for pharmaceutical companies is Article 27, which requires that patents "be available for any inventions, whether products or processes, in all fields of technology."<sup>89</sup> Another important part of TRIPS is the requirements it set forth for the use of compulsory licensing, which allows drug manufacturers to use a patent without the patent holder's permission.<sup>90</sup> The TRIPS agreement allows for the use of compulsory licenses when "the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions."<sup>91</sup> Moreover, Article 31 of the agreement states that member nations can waive the reasonable commercial efforts in "case[s] of a national emergency or other circumstances of extreme urgency or in [the] case[ ] of public noncommercial use."<sup>92</sup> Compulsory licensing is also limited to predominately supply the "domestic market of the Member authorizing such use" and that the license is terminated "when the circumstances which led to it cease to exist and are unlikely to recur."<sup>93</sup>

While TRIPS is a formal document, the purpose of the agreement was never to have "all signatories adopt the TRIPS legal text word-for-word

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85. Juan Bacalski, *Mexico's Pharmaceutical Patent Dilemma and the Lesson of India*, 23 ARIZ. J. INT'L & COMP. L. 717, 740 (2006).

86. Barton, *supra* note 1, at 147.

87. *Id.*

88. Jiao, *supra* note 4, at 661.

89. General Agreement on Tariffs and Trade: Multilateral Trade Negotiations Final Act Embodying the Results of the Uruguay Round of Trade Negotiations, Apr. 15, 1994, 33 I.L.M. 1125, 1208.

90. Yu, *supra* note 5, at 860.

91. *Id.*

92. *Id.*

93. Yu, *supra* note 5, at 860-61.

and adhere to it.”<sup>94</sup> Rather, the TRIPS agreement is supposed to provide minimum standards and goals, while allowing the individual countries to integrate those standards into their own national legislation.<sup>95</sup> Article 1 notes that member states are “free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system.”<sup>96</sup> Therefore, member states are entitled to flexibility in determining their own national pharmaceutical policies and enforcement mechanisms.<sup>97</sup>

## VII. DOHA DECLARATION AND ADDRESSING PUBLIC HEALTH NEEDS

As pandemics such as HIV/AIDS continue to grow and threaten the existence of many nations, activists around the world demand a relaxation of the “stranglehold [that] patent holders h[o]ld over life-saving medicines.”<sup>98</sup> In 2001, Zimbabwe, on the behalf of Africa, “demanded that the TRIPS council convene a special session on access to medicines.”<sup>99</sup> At this special session, the United States and European Union advanced pro-pharmaceutical positions while developing countries stressed the need for medication to address their public health crises.<sup>100</sup> The developing countries advanced the position that they have a broad range of public health problems not limited to HIV/AIDS, and are concerned with the lack of research that goes into the “neglected diseases.”<sup>101</sup> Moreover, developing countries wanted the recognition that patents increase prices and impede access to many necessary medications.<sup>102</sup> Therefore, developing countries wanted to freely use the TRIPS flexibilities, “includ[ing] the compulsory licensing and parallel importation without being threatened by developed countries.”<sup>103</sup> In addition, the developing world also wanted to eliminate the “predominately for domestic use” provision of Article 31, and outsource generics from domestic markets.<sup>104</sup>

These demands lead to the creation of the Doha Declaration (Declaration on the TRIPS Agreement and Public Health) in 2001.<sup>105</sup> The declaration confirmed that TRIPS “should be interpreted and implemented in a manner supportive of WTO members’ right to protect public health

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94. Brigitte Binkert, *Why the Current Global Intellectual Property Framework Under TRIPS is Not Working*, 10 INTELL. PROP. L. BULL. 143, 144 (2006).

95. *Id.*

96. Yu, *supra* note 5, at 864.

97. Binkert, *supra* note 95, at 145.

98. Brook Baker, *Arthritic Flexibilities for Accessing Medicines: Analysis of WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, 14 IND. INT’L & COMP. L. REV. 613, 623 (2004).

99. *Id.* at 623-24.

100. *Id.* at 624.

101. *Id.*

102. *Id.*

103. *Id.*

104. *Id.*

105. Barton, *supra* note 1, at 149.

and, in particular, to promote access to medications for all.”<sup>106</sup> The declaration allowed countries to use exceptions in TRIPS to the compulsory licensing provision to address “public health crises, including those related to HIV/AIDS, tuberculosis, malaria and other epidemics [that] can represent a national emergency.”<sup>107</sup> While the agreement states that the member nations “recognize the gravity of the public health problems afflicting many developing and least developed countries”<sup>108</sup> and agree that the “TRIPS agreement does not and should not prevent members from taking measures to protect public health,”<sup>109</sup> the “Doha Declaration left a technical legal problem unresolved.”<sup>110</sup> The problem involves compulsory licensing for countries that lack manufacturing capabilities themselves.<sup>111</sup> Paragraph six of the Doha Declaration recognized that states without manufacturing capabilities could face problems in making effective use of compulsory licensing and “instruct[ed] the council for TRIPS to find an expeditious solution to this problem and report it to the General Council before 2002.”<sup>112</sup> By 2002, all countries except the United States agreed to a procedure that allowed for the use of compulsory licensing in order to meet the problems addressed in the Doha Declaration.<sup>113</sup> The procedure allows generics that were created under compulsory licenses to be exported to countries that lacked manufacturing capacity.<sup>114</sup> However, the United States feared that this grant would be expanded to cover other types of products and was unwilling to accept such a prospect.<sup>115</sup> In 2003, the United States finally reached a compromise and agreed to the procedure as long as the chairperson of the General Council of WTO made statements recognizing the United States’ concerns.<sup>116</sup> To placate the United States, the chairperson made the statement that “the agreement would be used ‘in good faith to protect public health’ and [would] not be ‘an instrument to pursue industry or commercial policy objectives.’”<sup>117</sup> He also stated that the WTO recognized “the need to respond to the industry’s concern that products produced under this agreement not be exported to major developed world markets.”<sup>118</sup>

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106. *Id.*

107. *Id.*

108. World Trade Organization, Ministerial Declaration of 14 November 2001: Declaration on the TRIPS Agreement and Public Health, 41 I.L.M. 755 ¶1 (2002) [hereinafter Doha Declaration].

109. *Id.* ¶ 4.

110. Barton, *supra* note 1, at 149.

111. *Id.*

112. Doha Declaration, *supra* note 108, ¶ 6.

113. Barton, *supra* note 1, at 149.

114. WORLD TRADE ORGANIZATION, *Compulsory Licensing of Pharmaceuticals and TRIPS*, [http://www.wto.org/English/tratop\\_e/trips\\_e/public\\_health\\_faq\\_e.htm](http://www.wto.org/English/tratop_e/trips_e/public_health_faq_e.htm) (last visited Nov. 17, 2008).

115. Barton, *supra* note 1, at 149.

116. *Id.*

117. *Id.*

118. *Id.*

Although the Doha Declaration will place more pressure on pharmaceutical companies to research neglected diseases and increase access to these medications, many problems remain unresolved.<sup>119</sup> One of the major issues that remains unresolved is how TRIPS and the Doha Declaration will affect middle income countries such as China, Mexico, Brazil, and India.<sup>120</sup> Unlike the least developed countries, middle-income countries have manufacturing capabilities and will most likely not be able to make use of the compulsory licensing exceptions.<sup>121</sup> For example, countries such as a Mexico and China agreed that they would only avail themselves of the compulsory licensing system if they were faced with “circumstances of extreme urgency.”<sup>122</sup> Furthermore, bilateral free trade agreements pre and post TRIP also greatly shape international patent regulation and remove many of the TRIP flexibilities.<sup>123</sup> For example, much of Mexico’s patent reform had taken place before 1995, in response to the passage of NAFTA. The next section will discuss the historical context of patent protection in Mexico and how international patent regulation has transformed the Mexican pharmaceutical industry.

#### VIII. AN OVERVIEW OF PATENT REGULATION IN MEXICO AND THE CURRENT STATE OF THE MEXICAN PHARMACEUTICAL INDUSTRY

The Mexican government established its ability to protect intellectual property through its constitution.<sup>124</sup> The Mexican Constitution of 1917 gives the government broad authority to regulate economic development and prohibit monopolies, except for certain governmental monopolies.<sup>125</sup> Mexico’s first attempt to develop a patent system occurred in 1975 when it passed the Law of Inventors.<sup>126</sup> The Law of Inventors was greatly influenced by the Calvo doctrine, which stressed the importance of nationalism in the drafting of laws. Therefore, the law was intended to aid Mexico’s industrial development and was not supportive of the inventor. Rather, it “eliminated the inventors’ rights by reducing its monopoly rights in patents, in order to benefit collective interests and increase the nation’s economic independence.”<sup>127</sup> In 1987, the Mexican government amended the Law of Inventors to comply with the Paris Convention and

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119. *Id.*

120. IAN FERGUSSON, CRS REPORT FOR CONGRESS: THE WTO, INTELLECTUAL PROPERTY RIGHTS AND THE ACCESS TO MEDICINES CONTROVERSY, 4 (2006) [hereinafter CRS Report].

121. Although the procedure allowed the exportation of generics created through compulsory licensing, many countries opted out. *Id.* at 6.

122. *Id.*

123. CENTER FOR INTERNATIONAL ENVIRONMENTAL LAW [CIEL], *The WHO & Intellectual Property in Bilateral Free Trade Agreements*, 1 (2006), [http://www.who.int/phi/public\\_hearings/first/15Nov06DalindyeboShabalala.pdf](http://www.who.int/phi/public_hearings/first/15Nov06DalindyeboShabalala.pdf).

124. Bacalski, *supra* note 85, at 724.

125. *Id.*

126. Farolan, *supra* note 73, at 54.

127. *Id.* at 57.

increased patent protection "from ten to fourteen years."<sup>128</sup> The greatest amount of transformation, however, occurred with the passage of NAFTA.

To foster modernization of Mexican industries and demonstrate its resolve to go through with the NAFTA negotiations, the Mexican government agreed to reform its intellectual property laws.<sup>129</sup> In response to NAFTA, Mexico passed the Law of Promotion and Protection of Industrial Property (IPL) in 1993.<sup>130</sup> The IPL increased patent protection from fourteen to twenty years from the filing date and also required products to be novel.<sup>131</sup> In addition, the Mexican government created the Mexican Institute of Industrial Property (IMPI).<sup>132</sup> This organization, which was formed under the Secretariat of Commerce, has the primary function of examining patents and "offer[ing] technical and professional help through a consulting service."<sup>133</sup> The IMPI also has policing functions and can "conduct inspections, gather information and [. . .] enforce violations to intellectual property rights."<sup>134</sup>

Currently, the Mexican pharmaceutical market is among the most developed in Latin America. In 2002, there were approximately 390 companies, both domestic and international, that manufactured pharmaceutical products in Mexico.<sup>135</sup> Most of the indigenous manufacturers in Mexico focus on generic drugs.<sup>136</sup> The market is split between public and private.<sup>137</sup> The public sector, which purchases drugs through governmental agencies, serves 60 to 70 percent of the population but accounts for only about 15 percent of the total financial value of the pharmaceutical market.<sup>138</sup> Prices in the public market are also cheaper and tend to be one-fifth of the price of comparable drugs sold in the private sector.<sup>139</sup> The drugs purchased by the public sector must be generics.<sup>140</sup> On the other hand, the private sector, or the Mexican pharmaceutical market, serves a smaller segment of the population but accounts for 85 percent of the financial value of the market.<sup>141</sup> Similar to the U.S. market, many of these companies are large multinational corporations that advertise and promote their products.<sup>142</sup> In contrast to the public market, the private market can sell both generic and brand name drugs.<sup>143</sup>

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128. *Id.*

*Id.*

129. *Id.* at 58.

130. *Id.* at 60.

131. *Id.* at 61.

132. *Id.* at 58.

133. *Id.*

134. *Id.*

135. Bacalski, *supra* note 85, at 732.

136. *Id.*

137. *Id.* at 733.

138. *Id.*

139. *Id.*

140. *Id.*

141. *Id.* at 734.

142. *Id.*

143. *Id.*

## IX. HOW INTELLECTUAL PROPERTY LAWS AFFECT ACCESS TO TB DRUGS IN MEXICO

Even before the implementation of NAFTA or TRIPS, the absence of strong patent protection did not prevent many multinational corporations from breaking into the Mexican market and gaining strong market shares.<sup>144</sup> In 1982, multinational firms controlled 72 percent of the pharmaceutical market, mainly in the private market.<sup>145</sup> Local firms concentrated their production mostly in the public field.<sup>146</sup> There was very weak participation of the local firms in the private market because the cost of competing and developing their own brand name in the private market was prohibitive, while the cost to enter the public market was relatively low.<sup>147</sup> Furthermore, because the public sector was the only buyer in the public market, domestic firms did not have the incentive “to invest in brand, image and commercialization.”<sup>148</sup> Consequently, this reluctance of local firms to enter into the private market contributed to the delay in the development of marketing skills.<sup>149</sup> Mexican domestic firms also “have not been very entrepreneurial [. . .] in R&D efforts for the development of new molecules.”<sup>150</sup> Therefore, even before patent protection was introduced in Mexico, multinational companies had already wedged their place in the private market, overshadowing many of the Mexican domestic firms and possibly delimiting the effect of monopoly pricing on drugs.

During the 1990s, Mexico experienced a strong period of decentralization in its pharmaceutical industry. The passage of legislation that eliminated barriers to foreign investment in Mexico and increased patent law protection led to greater market concentration of large firms.<sup>151</sup> The number of pharmaceutical firms dropped from 225 at the end of the 1980s to 178 at the end of 2000.<sup>152</sup> Many of the firms disappeared or were acquired by multinational firms.<sup>153</sup> The private market increased from 72 percent in 1982 to almost 80 percent in 1998 to 1999.<sup>154</sup> The public market accounted for approximately 15 percent while the generic sector accounted for 5 to 6 percent.<sup>155</sup>

The introduction of patent protection has been followed by an upward swing in drug prices. Between 1992 and 1993, prices increased by 20 to 25

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144. Maria Pluvia Zuniga & Emmanuel Combe, *Introducing Patent Protection in the Pharmaceutical Sector: A First Evaluation of the Mexican Case*, 16 REVUE RÉGION ET DÉVELOPPEMENT 192 (2002).

145. *Id.* at 202.

146. *Id.*

147. *Id.* at 204.

148. *Id.*

149. *Id.*

150. *Id.* at 205.

151. *Id.* at 204.

152. *Id.*

153. *Id.*

154. *Id.*

155. *Id.*

percent.<sup>156</sup> However, because most TB drugs are off-patent, the introduction of patent regulation is not likely to affect the price of current TB drugs.<sup>157</sup> Patent protection, however, stimulates the production of more “me-too” drugs, which are very similar, modified versions of drugs already on the market.<sup>158</sup> Patents create this incentive because the creation of imitative drugs instead of innovative drugs requires less research, less money, and guarantees quicker patents.<sup>159</sup> Most domestic Mexican firms will be unable to pursue innovative drugs because, unlike multinational corporations, they lack the infrastructure and resources to develop new molecules.<sup>160</sup> Therefore, in order to compete Mexican firms may try to emerge on the private market as generic producers of already off patent medications.<sup>161</sup> Since the private market in Mexico tends to serve the wealthiest population, this shift of local companies into the private market may result in “difficulties to access new and better medicines which would be commercialized only for the rich market.”<sup>162</sup>

Aside from the possibility of creating an incentive to develop “me-too” drugs, the effect of patents law on overall R&D priorities is ambiguous.<sup>163</sup> The presence of patents may create financial incentive for the pharmaceutical firms to concentrate R&D in specific, profit-making, first world diseases.<sup>164</sup> On the other hand, it may lead to more investment in diseases that plague other parts of the world because “international markets are without a doubt one of the most important elements for pharmaceutical patents.”<sup>165</sup> Thus, there is a chance that with the introduction of patents there may be more research into TB medications. However, ten years after the introduction of patents in Mexico, technological creation in Mexico is negligible.<sup>166</sup> Determining the effect of patents on R&D is premature at this point because it takes up to eight to ten years for a chemical entity to be developed.<sup>167</sup> Therefore, at a later point, further research is needed to determine the actual affect of pharmaceutical patents on R&D in Mexico.<sup>168</sup>

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156. *Id.* at 206.

157. Audio tape: Interview with Medical Anthropologist Dr. Paul Farmer, interview by National Public Radio (Sept. 25, 2003), <http://www.npr.org/templates/story/story.php?storyId=1446061>.

158. Zuniga, *supra* note 146, at 195.

159. See generally Peter Lansbury, *An Innovative Drug Industry? Well, No*, WASHINGTON POST, Nov. 16, 2003 at B02, available at <http://www.washingtonpost.com/ac2/wp-dyn/A43257-2003Nov14?language=printer> (noting that in the United States, the development of me-too drugs is common because modified versions of already existing drugs are patentable and profitable).

160. Zuniga, *supra* note 146, at 211.

161. *Id.* at 212.

162. *Id.*

163. *Id.* at 211.

164. *Id.*

165. *Id.*

166. *Id.* at 212.

167. *Id.*

168. *Id.*



If an innovative drug is introduced on the market, the introduction of stronger patent law creates entry barriers for generic companies because these companies will be prohibited from entering the market when the patent is in effect.<sup>169</sup> The entry barrier is also exacerbated by multinational corporations that attempt to prolong the monopoly even after the expiration of the patent.<sup>170</sup> This limitation of generic competition is relevant to the access to TB drugs. If new TB drugs are invented they will be subject to these patent regulations, prohibiting generic companies from competing and reducing prices.<sup>171</sup> Furthermore, the prohibition of generic competition of patented drugs further weakens Mexican domestic producers.<sup>172</sup> Domestic producers will not be able to produce generic versions of new drugs and produce income from exportation.<sup>173</sup> Fostering a strong generic industry is important to tackling diseases endemic to the population.<sup>174</sup> Through encouraging a strong generic market in middle-income countries, domestic companies will gain more resources to invest in the development of new innovative drugs, possibly leading to greater research into neglected diseases.<sup>175</sup> However, currently Mexico's exports are weak and will continue to weaken as patent laws strengthen.<sup>176</sup>

## X. CONCLUSION

Mexico, like many middle-income countries, is a place of economic contradictions.<sup>177</sup> While it is the eighth largest trading power in the world, and one of the richest countries in Latin America,<sup>178</sup> in 2002 half the Mexican population was living in poverty, and one fifth of the population was living in extreme poverty.<sup>179</sup> Mexico is a place where tuberculosis still plagues its population and leads to approximately 2,248 deaths per year.<sup>180</sup>

Unlike developed countries such as the United States, Mexico does not have the same domestic capabilities and infrastructure to produce new

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169. *Id.* at 207.

170. *Id.*

171. CRS Report, *supra* note 121, at 38.

172. See Jiao, *supra* note 4, at 670-672 (noting that partially developed countries such as South Africa or India benefit from weakened patent laws because they allow the domestic market to grow).

173. *Id.* at 673.

174. *Id.*

175. *Id.*

176. Zuniga, *supra* note 146, at 207 (stating that exports in Mexico are weak due to tariff barriers and costly approval standards required abroad).

177. See generally Jiao, *supra* note 4, at 670.

178. See generally Gomez, *supra* note 71, at 53.

179. THE WORLD BANK, *Poverty in Mexico – Fact Sheet*, <http://web.worldbank.org/WBSITE/EXTERNAL/COUNTRIES/LACEXT/MEXICOEXTN/0,,contentMDK:20233967~pagePK:141137~piPK:141127~theSitePK:338397,00.html>.

180. WORLD HEALTH ORGANIZATION, *TB Country Profile for Mexico*, [http://www.who.int/globalatlas/predefinedreports/tb/PDF\\_Files/mex.pdf](http://www.who.int/globalatlas/predefinedreports/tb/PDF_Files/mex.pdf) (last visited Nov. 23, 2008).

drugs.<sup>181</sup> Even if Mexican pharmaceutical companies were able to produce new drugs, they would not be able to enjoy patent protection at the same level of many multinational companies.<sup>182</sup> Because domestic Mexican companies are relatively weak compared to their multinational counterparts,<sup>183</sup> they do not have the infrastructure necessary to enforce their patents.<sup>184</sup> It is important to remember that, "[t]here is a crucial difference between a patent system that allows international companies to effectively enforce their domestic patents and a patent system that allows an emerging domestic industry to protect its intellectual property internationally."<sup>185</sup> It appears that the international patent system incorporated in Mexico has encouraged multinational companies to enforce patents rather than domestic companies. Having a strong domestic pharmaceutical industry is advantageous to the public health and wellbeing of the country.<sup>186</sup> Many multinational corporations are driven by profit instead of the pressing public health needs of international populations.<sup>187</sup> Domestic producers in Mexico, however, may have more of a vested interest in the health of the population and will be more likely to manufacture TB drugs. Under the international patent law system, there is very little room for Mexican domestic producers to grow. Therefore, having a weak intellectual property law system that gives domestic companies the flexibility to develop and innovate will likely lead to greater access to certain drugs.<sup>188</sup>

It can be argued that the implementation of NAFTA or TRIPS did not have a large impact on access to TB drugs for two main reasons. First, multinational corporations were already present in the Mexican market prior to the implementation of patents,<sup>189</sup> and second, most of the TB drugs available are already off patent.<sup>190</sup> Nevertheless, stronger patent laws may hinder effective long-term TB control. Patent laws create an incentive to pursue too many drugs rather than innovative medications that would help quell the epidemic.<sup>191</sup> As previously mentioned, the complexity of the TB regimen, potential side effects, and emerging resis-

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181. See Zuniga, *supra* note 146, at 205 (explaining that domestic firms have not had the incentive to develop new drugs or commercialize due to the large presence of multinational corporations).

182. *Id.*

183. *Id.*

184. Jiao, *supra* note 4, at 672 (explaining that South Africa, as a middle income country, is not at the stage where individual companies have infrastructure to enforce their patents).

185. *Id.*

186. *Id.* at 673 (explaining that when diseases are endemic to an area the local pharmaceutical company has additional incentive to innovate and research in regards to those diseases).

187. *Id.*

188. *Id.*

189. Zuniga, *supra* note 146, at 205.

190. Audio tape, *supra* note 159.

191. Zuniga, *supra* note 146, at 195.

tance demand greater research into TB medication.<sup>192</sup> If, however, patents encourage pharmaceutical companies to pursue profit-making medications prevalent in the developed world instead of neglected diseases such as TB, countries such as Mexico may not be able to meet the challenges faced by this epidemic.

The existence of stringent global patent laws is a reality that Mexico has dealt with for more than a decade.<sup>193</sup> The stringent patents may be beneficial as they provide incentives for research and development.<sup>194</sup> But the likelihood of this research meeting the demands of neglected diseases such as TB is more questionable.<sup>195</sup> To help alleviate the possibility of neglected diseases becoming even more neglected, the Mexican government has taken important strides in making sure that the public health demands of its population are met.<sup>196</sup> For example, the Mexican government implemented the 1997 General Law of Health that promotes the production of generic drugs.<sup>197</sup> The government is also in the process of developing a universal social insurance scheme to make sure that the fifty million uninsured Mexicans have the ability to pay for medication and other health care needs.<sup>198</sup>

In addition to changes in governmental policy, changes in pharmaceutical incentive schemes may help alleviate the possible negative effect of patents.<sup>199</sup> For example, by implementing financial rewards to pharmaceutical companies for positive health care outcomes, companies may have more of an incentive to produce drugs based on the public health care needs of a society.<sup>200</sup> Furthermore, by creating "open access drug discovery entities," which are institutions for academic and industry collaboration, there may be more research into neglected diseases such as TB.<sup>201</sup> Therefore, while patents may negatively affect access to and innovation of certain types of drugs, there are possible solutions to counter

192. Richard J. O'Brien & Andrew A. Vernon, *New Tuberculosis Drug Development: How Can We Do Better?*, 157 AM. J. RESPIR'Y & CRIT. CARE MED. 1705 (1998).

193. Zuniga, *supra* note 146, at 203.

194. CRS Report, *supra* note 121, at 11.

195. Ellen't Hoen, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*, 3 CHI. J. INT'L L. 27, 46 (2002).

196. Julio Frenk et al., *Comprehensive Reform to Improve Health System Performance in Mexico*, 368 LANCET 1524, 1524 (2006).

197. Zuniga, *supra* note 146, at 203.

198. Frenk, *supra* note 198, at 1524.

199. Symposium, *No Time to Wait: Overcoming Gaps in TB Research and Development*, <http://www.doctorswithoutborders.org/events/TbSymposium/summary.cfm> (2007).

200. *Id.*

201. *Id.* "Open access drug discovery entities can be envisioned as contract-based frameworks and sites for collaborations between academics and industry and among companies. Pharmaceutical companies would be enlisted as hosts in several geographic regions and, on a fee for service basis, open sectors of their R&D facilities to approved scientists from academia or other drug companies." *Id.* As MSF states, this kind of collaboration "would offer a crucial logistic solution, allowing close collaboration among academic and industry scientists and eliminating the drawbacks of managing virtual drug discovery within large international consortia." *Id.*

the effect.<sup>202</sup>

The effect of patents on TB is under researched and much is left to speculation.<sup>203</sup> This may be due to the fact that many of the TB drugs are off-patents, and therefore, stringent patent laws may not greatly affect the current drugs.<sup>204</sup> This note does not attempt to positively assert that patents will necessarily negatively affect TB innovation or access, nor does it attempt to say that the presence of patents will increase access and innovation in the field of TB. Instead this paper attempts to give a general overview of international patent laws and give some insight as to how patent laws may affect the TB epidemic in a middle-income country such as Mexico.

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202. *Id.*

203. *Id.*

204. Audio tape, *supra* note 159.

